FEB 13 2006 PE 13 2006

<u>PATENT</u>

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: SIMMONS ET AL. Examiner: P. HUYNH

Serial No.: 10/764,428 Group Art Unit: 1644

Filed: JANUARY 23, 2004 Docket No.: 11669.120USU1

Confirmation No.: 6080 Customer No.: 23552

Title: METHODS FOR PRODUCING HUMANIZED ANTIBODIES AND

IMPROVING YIELD OF ANTIBODIES OR ANTIGEN BINDING

FRAGMENTS IN CELL CULTURE

**CERTIFICATE UNDER 37 CFR 1.10**:

"Express Mail" mailing label number: EV 639593725 US

Date of Deposit: February 13, 2006

I hereby certify that this paper or fee is being deposited with the U.S. Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to Commissioner for Patents, Mail Stop Amendments, Commissioner for Patents P.O. Box 1450 Alexandria, Viginia 22313-1450.

Name: Sheryl A. Boerboom

# RESPONSE TO RESTRICTION REQUIREMENT

Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

Dear Sir:

This paper is being submitted in response to the Restriction Requirement mailed January 12, 2006, said period of response being extended from February 12, 2006, which was a Sunday, extending the time for response to Monday, February 13, 2006. While not acquiescing to the Examiner's reasoning, Applicants elect Group I, including claims 1-74 and 82-127 with traverse.

Applicants traverse the restriction with respect to Group I, including claims 1-74 and 82-127 and to Group II, claims 1-74 and 82-127. Applicants submit that the Examiner has improperly restricted the claims to a single species. Applicants respectfully submit that the law requires that a genus claim be searched and examined, as well as a reasonable number of species. See 37 CFR 141

## § 1.141 Different inventions in one national application.

(a) Two or more independent and distinct inventions may not be claimed in one national application, **except** that more than one species of an invention, not to exceed a reasonable number, may be specifically claimed in different claims in one national application,

provided the application also includes an allowable claim generic to all the claimed species and all the claims to species in excess of one are written in dependent form (§ 1.75) or otherwise include all the limitations of the generic claim.

The methods of the invention are directed to methods of producing an antibody or antigen-binding fragment in high yield. This method is applicable to all antibodies or fragments thereof regardless of the specificity of the antibody. Antibodies or fragments thereof provide a genus of compounds with related chemical structure and function and therefore, would not be unduly burdensome to search. Anti-VEGF antibodies and anti-IgE antibodies represent a subgenus of antibodies. In accord with 37 CFR 1.141, Applicant's request reconsideration of the restriction requirement because it would not be unduly burdensome to search a genus claim and more than one species based on the related structural, and functional properties of the claimed method directed to a genus of antibodies. The Examiner may require an election of species but if that species is found to be patentable, additional species should be searched. To not search Applicants' method claim directed to an antibody or antigen-binding fragment thereof does not allow Applicants to claim the full scope of their invention and that is contrary to the law and the rules.

Moreover, Applicants also traverse the restriction requirement because Applicants submit that the Examiner has not established that it would be unduly burdensome to search both of these groups as they are classified in the same class and subclass. Moreover, a search of this method concerning production of an antibody or antigen-binding fragment is likely to include references for antibodies of different specificities.

Applicants further traverse the restriction requirement with respect to the subject matter of the group III and IV claims. Applicants submit, that at least for the same reasons presented above, the restriction between these two groups is improper and the examiner has not established that the search of the subject matter of both groups would be unduly burdensome.

#### **INTERVIEW**

Applicants request an interview with the Examiner and his supervisor before the restriction is finalized. Applicants request that the Examiner contact Applicants representative to schedule the interview.

### **SUMMARY**

Based on the foregoing, Applicants respectfully request rejoinder of the claims of Group I and Group II and a search of the full scope of Applicants' claims. Examination on the merits is requested

Respectfully submitted,

MERCHANT & GOULD P.C. P.O. Box 2903 Minneapolis, Minnesota 55402-0903 (612) 332-5300

Date: <u>Jebrucey 13, 2006</u>

Katherine M. Kowalchyk

Reg. No. 36,848

23552
PATENT TRADEMARK OFFICE